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| 10/562,777      | 07/07/2006  | Michael J. Yaszemski | 630666.00008        | 4282             |

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| EXAMINER |
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LISTVOYB, GREGORY

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| ART UNIT | PAPER NUMBER |
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1796

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

01/06/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/562,777 | <b>Applicant(s)</b><br>YASZEMSKI ET AL. |  |
|                              | <b>Examiner</b><br>GREGORY LISTVOYB  | <b>Art Unit</b><br>1796                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,9 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Jo et al (US 2002/0028189) herein Jo as evidences by Xie et al (Experimental investigation on the reliability of routine SEC-MALLS for the determination of absolute molecular weights in the oligomeric range, Polymer Vol 43, issue 14, 2002, pp 3973-3977) herein Xie (all cited in the previous Office Action).

Jo teaches oligomers based on polyethylene glycol (PEG) and fumaric acid (see Abstract), where PEG has number average molecular weight (Mn) within the range of 1000-4600 and resulting polymer has Mn within the range of 1260-11610 (see Table 1, particularly entry 2, where Mn of the polymer is 3960).

Jo discloses that PEG can be equivalently replaced by another biodegradable macromonomer, such as end-hydroxylated polycaprolactone (see line 0036).

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's

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disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to interchangeably apply polyethyleneglycol and end-hydroxylated polycaprolactone, because they are equivalent in Jo's disclosure and they are known materials based on their suitability for its intended use.

Regarding new limitation of claim 2 claiming a self-crosslinkable polymer, Specification of the Application examined teach that this property is possible due to the presence of unsaturated double bonds, which belong to fumaric acid residues (see Abstract). However, Jo's polymer has the same residues and therefore, it is also self-cross-linkable.

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In reference to claim 9, Jo teaches the reaction between PEG or end-hydroxylated polycaprolactone and fumaryl chloride (see Abstract and line 0036).

Jo does not teach the claimed range of polymer molecular weight.

However, note that Jo determines absolute molecular weight, since he uses calibration, based on end groups number, which is determined by NMR (see line 0071).

In opposite, Applicant discloses relative molecular weight, based on Polystyrene calibration (see line 0036 of Specification). The value obtained can be up to 2-3 times different from the absolute numbers, because of hydrodynamic radii of aliphatic copolymer. In addition, adsorption of end group on the column can significantly broaden molecular weight distribution, especially in the case, where  $M_n$  is low (i.e. 3000-4000).

Xie evidences that GPC method used calibration with polymer standards with unrelated structures, creates significant over- or under- estimation of the real values (see page 3976, right column).

In addition, Molecular Weight Distribution, disclosed by the Applicant is significantly higher than expected, based on Carothers' equation:  $X_n = 1/(1-p)$ , where  $X_n$  is number of units in macromolecule and  $p$  is conversion. Theoretical MWD is equal to 2, but for oligomers its value is between 1 and 2.

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The position is taken that absolute MWD values of Application and Jo's polymers are equal, since the same monomers are used.

Regarding limitations, claiming melting and hardening points range, since the structure of Jo's and applicant's polymers is identical, the same physical properties are expected.

### ***Response to Arguments***

Applicant's arguments filed 9/22/2009 have been fully considered but they are not persuasive.

Applicant submits that Jo does not teach a self-crosslinkable copolymer as claimed in Claim 2 of the present invention.

This is incorrect. Since Jo's polymer has the same unsaturated carbon-carbon bonds, as the claimed structure, Jo's polymer is also self-crosslinkable. Note that cross-linkable does not mean cross-linked. It shows intended action, but not a specific cross-linking structure.

Applicant argues that Jo uses different set of monomers compare to ones of the Application examined.

Examiner disagrees. Jo uses Polycaprolactam diol and fumaril chloride, resulting in the corresponding copolymer (see line 0036).

Applicant argues about Examiner statement that absolute molecular weight is different from relative one.

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Examiner disagrees. GPC method based on comparison of hydrodynamic volumes of standards (in the Application examined it is polystyrene) and the sample polymer (which is polycaprolactone-fumarate). At the same molecular weight of the standard and the polymer their hydrodynamic volumes are clearly different. Note that Xie used in the rejection to demonstrate that if GPC method used calibration with polymer standards with unrelated structures, it creates significant over- or under-estimation of the real values (see page 3976, right column).

Applicant submits that Jo's and Applicant's polymers have significantly different physical properties (i.e. Modulus)

However, the above properties are not claimed. In addition, this statement is not supported by the data. Applicant can submit an experimental data, directly comparing Jo's polycaprolactam-fumarate polymer and corresponding material from the Application.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James J. Seidleck/

Supervisory Patent Examiner, Art Unit 1796

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